



**The Hepatitis C Mentor & Support Group  
PATIENT SUPPORT NEWSLETTER**

Vol. 3 2017

**WELCOME from Ronni Marks, Founder & Director HMSG**

I have been working to raise awareness for Hepatitis C for over twenty years. I started my journey as a patient, became a patient advocate, and the organizer and facilitator of one of the longest running and successful support groups at a major hospital in New York City. Seeing a lack of education and supportive services for HCV, I founded the organization, **HMSG-The Hepatitis C Mentor and Support Group, Inc.** in 2011.

After several unsuccessful attempts with other treatments, three years ago after treating with the new DAA's, I was told the HCV virus was no longer detected in my body. This has reinforced my mission to help others to have the same opportunity.

My hope is that this newsletter will be a form of education and support to those newly diagnosed, those living with HCV or Co-infected HCV/HIV, those having to make decisions, those on treatment and even post treatment. We welcome your suggestions on what you would like to see in upcoming issues and any stories you want to share. We can be contacted at [hepatitisCmsg@gmail.com](mailto:hepatitisCmsg@gmail.com).

**HEPATITIS C TREATMENT UPDATE:**

**Matthew Akiyama, MD, MSc - Assistant Professor of Medicine, Montefiore Medical Center  
Medical Advisor to HMSG**

Much progress has been made since the emergence of Direct Acting Antivirals (DAAs) for the treatment of HCV. DAAs were developed to improve the tolerability and efficacy of HCV treatment regimens by targeting proteins on the HCV viral genome including the NS3/4A protease, NS5A, and NS5B polymerase. Inhibiting these proteins during viral replication prevents the virus from reproducing and leads to eradication of the virus from liver cells.

The first DAAs to receive FDA approval in 2011 were protease inhibitors called Victrelis (boceprevir) and Incivek (telaprevir). Olysio (simeprevir), another protease inhibitor, and Sovaldi (sofosbuvir), a nucleotide polymerase inhibitor, were approved two years later in 2013. Initially these DAAs were used in combination with pegylated interferon and ribavirin; however, their use was restricted to patients with HCV genotypes 1 and 4. Later in 2013, sofosbuvir was approved for treatment of patients with HCV genotypes 2 and 3 in combination with ribavirin.

The first all oral DAA regimen for HCV genotype 1 was sofosbuvir/simeprevir plus ribavirin approved in 2014. Harvoni (sofosbuvir/ledipasvir) was the first DAA to be approved for use without ribavirin in October 2014. Viekira Pak (parataprevir/ritonavir, ombitasvir, dasabuvir) was approved shortly thereafter for use with and without ribavirin.

In 2015, Daklinza (daclatasvir) an NS5A was approved for use with sofosbuvir for genotype 3, which was a major advancement since ribavirin was no longer required for these genotypes. Technivie, a combined single tablet regimen containing paritaprevir/ritonavir/ombitasvir, was also approved in 2015 for treatment of HCV genotype 4.

In 2016, Zepatier (grazoprevir/elbasvir) a new NS3/NS5a combination was approved by the FDA on January 28<sup>th</sup>, 2016 for genotypes 1 and 4. The first pan genotypic agent velpatasvir to be used in combination with sofosbuvir (Epclusa) was approved on June 28<sup>th</sup>, 2016.

This year, two new pan genotypic regimens have been approved: Vosevi (voxilaprevir velpatasvir/sofosbuvir), an NS3/4A, NS5A, NS5B combination therapy, and Mavyret (glecaprevir/pibrentasvir) an NS3/4A, NS5A combination therapy. Both new therapies are approved for patients with genotypes 1-6 with no or mild cirrhosis. Vosevi is the first treatment approved for patients who have been previously treated with Sofosbuvir or NS5A inhibitors. Mavyret is approved for patients with genotype 1 who have been previously treated with an NS5A inhibitor or an NS3/4A protease inhibitor. Mavyret is the first treatment of 8 weeks duration approved for all HCV genotypes 1-6 in patients without cirrhosis who have not been previously treated. Standard treatment length was previously 12 weeks or more. Mavyret is also approved for patients with moderate to severe kidney disease and those who are on dialysis.

The following is a timeline of DAA combinations including those through mid-2017.

Trade name	Generic name(s)	Class	Use/efficacy	FDA status
Victrelis	boceprevir	NS3/4A	Genotype 1 (~67% <sup>1</sup> )	Approved 5/4/11
Incivek	telaprevir	NS3/4A	Genotype 1 (75% <sup>2</sup> )	Approved 5/23/11
Olysio	simeprevir	NS3/4A	Genotype 1 (~80% <sup>3</sup> )	Approved 11/22/13
Sovaldi	sofosbuvir	NS5B	Genotype 1, 4 (~90% <sup>4</sup> )	Approved 12/6/13
Olysio + Sovaldi	simeprevir + sofosbuvir	NS3/4A + NS5B	Genotype 1 (~92% <sup>5</sup> )	Approved 11/5/14
Harvoni	ledipasvir/sofosbuvir	NS5A/NS5B	Genotype 1,4,5,6 (up to 100% <sup>6</sup> )	Approved 10/10/14
Viekira Pak	parataprevir/ritonavir, obitasvir, dasabuvir	NS3/4A, NS5A, NS5B	Genotype 1 (up to 100% <sup>7</sup> )	Approved 12/19/14
Daklinza + Sovaldi	daclatasvir + sofosbuvir	NS5A + NS5B	Genotype 3 (up to 98% <sup>8</sup> )	Approved 7/24/15
Technivie	parataprevir/ritonavir, obitasvir	NS3/4A, NS5A, NS5B	Genotype 4 (91% <sup>9</sup> )	Approved 7/24/15
Zepatier	grazoprevir/elbasvir	NS3/4A/NS5A	Genotype 1,4 (up to 100% <sup>10</sup> )	Approved 1/28/16
Epclusa	velpatasvir/sofosbuvir	NS5A/NS5B	Genotype 1,2,4,5,6 (99% <sup>11</sup> )	Approved 6/28/16
Vosevi	voxilaprevir velpatasvir/sofosbuvir	NS3/4A, NS5A, NS5B	Genotype 1,2,3,4,5,6 (99% <sup>12</sup> )	Approved 7/18/17
Mavyret	glecaprevir/pibrentasvir	NS3/4A, NS5A	Genotype 1,2,3,4,5,6 (99% <sup>13</sup> )	Approved 8/3/17

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**\* SITE FOR CHECKING DRUG-INTERACTIONS\***

<http://www.hep-druginteractions.org>

**\*TREATMENT SIDE EFFECT MANAGEMENT TIPS\***

For nausea. Ginger can be taken to decrease the nausea. It can be eaten raw or in foods that contain ginger, such as ginger tea, ginger ale, and ginger candy.

**SEVEN QUESTIONS TO ASK ABOUT MEDICATIONS:**

Doctors should communicate these basic points whenever they prescribe a new medication. Unfortunately, research shows they usually deliver only about four of them. For the full story, ask these critical questions when you are given a new drug:

1. What's the name (trade) of the medication?
2. Why are you prescribing it for me?
3. What are the potential side effects?
4. How much should I have (how many pills, squirts, teaspoons, etc.)?
5. How many dose(s) do I need each day, and what time should I take them?
6. Will this medication interact with my current medications or with over the counter products I currently take, such as antacids and others?
7. For how long should I take the medication?

**Many patients say they are handed their lab work results, but do not understand them. Hopefully the following will help:**

**LAB DEFINITIONS:**

**WBC- "White Blood Cell Count" - Normal Range (4.5-11 x 10<sup>9</sup> per µL)**

*White Blood Cells are cells that fight infection and can cause inflammation. This number can be elevated or decreased in a new infection. It may present low in infections harming the immune system such as HIV.*

**ANC- "Absolute Neutrophil Count" - Normal Range (>500 cells)**

*The ANC is a number representing the specific number of neutrophils within the white blood cell count (WBC). Neutrophils are the main infection fighting cell in a new infection. In situations where the total WBC is low, the ANC indicates the body's ability to fight an acute infection.*

**Hg- "Hemoglobin" - Normal Range (Male- 13.5-17.5g/dL / Female- 12-16 g/dL)**

*Hemoglobin is a protein component of red blood cells that uses iron to carry oxygen. When hemoglobin is low, this is called "Anemia."*

**Hct- "Hematocrit"- Normal Range (Male- 39-49% / Female - 35-45%)**

*Hematocrit represents how much blood volume is made up of red blood cells (RBC). If elevated, this indicates an increased production of red blood cells or a decreased amount of fluid without a change in red blood cells such as in dehydration. If lower, this indicates a decrease in red blood cell production.*

**PLT- "Platelet" - Normal Range (150-450 x 10<sup>3</sup> per µL)**

*Platelets are necessary to form clots in the body. Low platelets can indicate a tendency for bleeding. A low platelet count is called "thrombocytopenia," this may be seen in HIV, Hepatitis C, or blood disorders.*

**BUN- “Blood Urea Nitrogen” - Normal Range (7-18 mg/dL)**

*Blood Urea Nitrogen is a break down product of normal human metabolism. It is excreted by the kidney. If elevated, it can indicate non-specific status changes including changes to blood volume or kidney function.*

**Cr- “Creatinine” - Normal Range (0.6 – 1.2 mg/dL)**

*Creatinine is a break down product of normal human metabolism. It is excreted by the kidney. If elevated, this number indicates damage to the kidney itself.*

**Albumin – Normal Range (3.5 – 5.5 g/dL)**

*Albumin is a protein made in the liver and found in the blood. It is an indicator of liver function.*

**AST- “Aspartate Aminotransferase” - Normal Range (7-40 U/L)**

*AST is a marker used to indicate damage to the liver cells. It is compared with ALT.*

**ALT- “Alanine Aminotransferase” - Normal Range (7-40 U/L)**

*ALT is a marker used to indicate damage to the Liver. It is compared with AST.*

**Bilirubin – Normal Range (.2-1.0 mg/dL)**

*Bilirubin is a breakdown product of red blood cells. It is also an indicator of liver function.*

**HCV Viral Load- “Hepatitis C Viral Load” - Normal Range (Not detected)**

*Hepatitis C Viral Load being elevated indicates an active infection because the viral load is a measurement of the presence of the virus in the bloodstream.*

**HIV Viral Load- “Human Immunodeficiency Virus Viral Load”- (Not detected)**

*HIV Viral load indicates the current state of the infection.*

**TSH- “Thyroid Stimulating Hormone”- Normal Range (<10 µU/L, >60yo Men 2-7.3 / Women 2-16.8)**

*TSH is a marker of thyroid function.*

**AFP - “Alpha-Fetoprotein”**

*AFP is a non-specific marker that may indicate liver cancer.*

**INR- “International Normalized Ratio”**

*Is a measurement of bleeding time, which is an indication of liver function?*

Tarek Aly –Medical student, Ross University School of Medicine *sourced the lab definitions from Dugdale, David C., and David Ziev" Complete Blood Count: MedlinePlus Online Encyclopedia. "US National Library of Medicine. National Institutes of Health, 19 Mar. 2012.*

## WHY HEPATITIS C SUPPORT GROUPS ARE MORE NECESSARY THAN EVER

*Ronni Marks, Blog 2017*

I have heard that some providers and others are questioning if there is still a need for Hepatitis C support groups. While I agree these groups are no longer needed for hand holding purposes as they were in the interferon era, they now have taken on a new look. These are some of the reasons I believe there is still a very important role for these groups.

As I travel the country training people, I see the lack of education about Hepatitis C, both from patients, as well as providers, particularly in rural areas. This is why I now refer to them as Educational Support Groups. For those of us who experienced treatment before the DAA's, the side effects of today are minimal. But for those who are treatment naïve, for some, side effects exist. While the treatments may be for a shorter time, some patients still need help in dealing with having Hepatitis C. Even after cure, I am seeing some patients return to groups stating that they are experiencing post treatment issues, both physically and psychologically. For some they are not aware that they need to follow up, for those with cirrhosis knowing they should be having an Ultra sound done every six or twelve months. These are some of the things patients have told me they have learned by attending a group not from their provider.

For those aware there is a cure, but have no access to treatment due to restrictions, this has impacted them psychologically. They feel "stigma" now more than ever. I have even had a few folks say it makes them feel "unworthy". This is to me is heartbreaking.

For those who do not have access right now, it is a good source for how one can maintain their health while awaiting treatment. For those who have cured, ensuring they stay cured and healthy. When working with people who inject drugs, I have heard too many times that they are not aware that they can become REINFECTED once cured. This message must be told loud and clear. Many are not aware that the virus can live on equipment.

There is a generation of young people who have become infected with Hepatitis C through use of injecting opioids and heroin sharing needles. More education in regard to transmission should be included in these groups.

The LGBTQ community are sharing needles for hormones and steroids. We need to be educating them. Women of child bearing age need to be educated on vertical transmission of Hepatitis C. Support groups can be a good source to find patients who may want to become advocates for their own health, as well as for others who cannot speak for themselves. Part of the group can be demonstrations to patients on the few easy steps it takes to call their local and state politician's office to help educate them on Hepatitis C. It is a good way to show patients how their voice matters!

I strongly urge those who are looking for education and support to join a group whether it is on line, in person, or thru tele-support.

If your organization, hospital or clinic is interested in training for facilitating and setting up a group, HCMSG can be instrumental in helping. (Free of charge) The Hepatitis C Education and Support Group Assistance Program. <http://www.hepatitiscmsg.org/the-hepatitis-c-education-and-support-group-assistance-program.html>  
<http://www.hepatitiscmsg.org/healthcare-provider-support-and-education-program.html>

**Patients must never give up hope!**

## CLINICAL TRIALS

New HCV treatment options in development may be available through participation in clinical trials. Clinical trials require that you meet the inclusion and exclusion criteria. To inquire about participation contact one of the centers below. These centers generally complete an intake interview and perhaps collect records. If you are a candidate for clinical trials, you will be offered a trial if one is available or contacted at a future date when a trial is available. TAG (Treatment Action Group) provides an excellent overview to clinical trials entitled: Guide to Clinical Trials for People with Hepatitis C - Second Edition by Matt Sharp and Tracy Swan. Please access it at the following address: <http://www.treatmentactiongroup.org/hcv/publications/2011/hcv-clinical-trials-guide>

**ClinicalTrials.gov** (a service of the National Institutes of Health-NIH) Provides regularly updated information about federally and privately supported clinical research in human volunteers. The Website gives information about a trial's purpose, who may participate, locations, and phone numbers. For more details, visit: [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

### CURRENT CLINICAL TRIAL CENTERS in the NYC Region:

#### **COLUMBIA UNIVERSITY MEDICAL CENTER**

Dr. Elizabeth Verna- Clinical Director, Center for Liver Disease and Transplantation  
M. Cristina Faló, PhD, Clinical Research Director, Center for Liver Disease and Transplantation  
Claudia Musat, MD, Senior Research Coordinator 212-305-3839

#### **CONCORDE MEDICAL GROUP**

Drs. Hillel Tobias/Edward Brettholz /Alex Sherman 212-889-5544

#### **MONTEFIORE MEDICAL CENTER**

Dr. Sam Sigal  
Mortadha Abd 718-920-6240

#### **MOUNT SINAI MEDICAL CENTER**

Dr. Douglas Dieterich  
Susana Seijo Contact for studies 212-241-1617

#### **NORTHWELL HEALTH SYSTEM**

Dr. David Bernstein  
Radica Palmer, RN 516-562-2082

#### **NYU HEPATOLOGY ASSOCIATES**

Therese Capobianco Research Coordinator 212-263-0155  
[therese.capobianco@nyumc.org](mailto:therese.capobianco@nyumc.org)

#### **WEILL CORNELL MEDICAL COLLEGE**

Dr. Robert Brown 646-962-4040  
Dr. Sonal Kumar  
Marlene Feron- Rigodon, RN

## PATIENT ASSISTANCE PROGRAMS

Most pharmaceutical companies offer help to patients who cannot afford the medications needed to treat Hepatitis C. You should work with your medical provider to select and contact programs for assistance.

### **Patient Access Network (PAN) Foundation:**

An independent non-profit organization that provides assistance to underinsured patients for their out of pocket medical expenses. PAN assistance covers multiple Hepatitis C medications and a patient's choice of medication does not influence the amount of assistance a patient is able to receive.

To learn more or to apply, visit [www.panfoundation.org](http://www.panfoundation.org) or call 1866-316-7263

### **Patient Advocate Foundation**

To provide Hepatitis C patients with hands-on case management support

**Hepatitis C Co-Pay Relief fund award**

**HIV, AIDS and Prevention Co-Pay Relief fund**

Learn more at [www.patientadvocate.org](http://www.patientadvocate.org)

**Hepatitis C CareLine-1800-532-5274**

### **Healthwell Foundation**

Patients, providers, and pharmacies can apply by visiting HealthWell at [www.HealthWellFoundation.org](http://www.HealthWellFoundation.org) or by calling 1-800-675-8416 Monday through Friday 9:00 a.m. to 5:00 p.m. to speak with a HealthWell representative.

Here's a link to our Hep C fund page that includes all of the fund information and eligibility requirements:

<https://www.healthwellfoundation.org/fund/hepatitis-c>

**For anyone in New York State with Medicaid insurance who has been denied, please contact the NYS Attorney General's Office helpline [1-800-428-9071](tel:1-800-428-9071) to speak with a patient advocate or complete a [form online](#) \***



## HEPATITIS C TREATMENT MEDICATIONS

Most pharmaceutical companies offer help to patients who cannot afford the medications needed to treat Hepatitis C. You should work with your doctor to select and contact programs for assistance.

For more information about Patient Assistance Programs, please check out the two following resources:  
[www.fairpricingcoalition.org](http://www.fairpricingcoalition.org) and <http://www.hepatitisCmsg.org/assistance-programs.html>

### Gilead

Vosevi (sofosbuvir/valpatasvir/voxilaprevir)

Epclusa (sofosbuvir/valpatasvir)

Harvoni (ledipasvir/sofosbuvir)

Sovaldi (sofosbuvir)

#### Gilead Patient Assistance Program

1-855-7-MYPATH (1-800-769-7284)

<http://www.mysupportpath.com>

### Merck

Zepatier (grazoprevir/elbasvir)

#### Merck Patient Assistance Program

<http://merckhelps.com/Programs.aspx>

Please call 1-800-727-5400

### Abbvie

#### MAVYRET (glecaprevir/pibrentasvir)

##### Patient Support Program

[www.mavyret.com](http://www.mavyret.com)

1877-6289-9738

If you wish us to email you the newsletter and/or just want to contact us with news, questions, thoughts, etc., please contact us at [hepatitisCmsg@gmail.com](mailto:hepatitisCmsg@gmail.com). Check out our website [www.hepatitisCmsg.org](http://www.hepatitisCmsg.org) for more information, support, and assistance.

Thank you!

*Support for this Newsletter was provided in part from the following:  
Gilead, AbbVie, Janssen, and Merck.*